K11 1465

SYBRON DENTAL SPECIALTIES

Section 5 - 510(k) Summary

JUL 25 2012

Submitter:

Sybron Dental Specialties, Inc.
1717 West Collins Avenue
Orange, California 92867
(714) 516-7602 - Phone
(714) 516-7488 - Facsimile
Wendy Garman - Contact Person

Date Summary Prepared: 10 July 2012

- Trade name – *Compothixo*
- Common name – Composite Modeling Instrument
- Classification name – Dental Hand Instrument, Class I (21 CFR §872.4565, DZN)

Devices for Which Substantial Equivalence is Claimed:

- Composite Instruments, Class I Medical Devices, Product Code DZN, Hu-Friedy

Summary

Device Description

Compothixo is indicated for modeling of composite, occlusal modeling, fissures and removal of excess composite, layer application technique, bulk technique in small cavities, and for direct veneering. Compothixo represents the next generation composite placement and modeling instrument suitable for all classes of restorations. Compothixo technology utilizes the thixotropic properties of composites by only changing viscosity, without altering the chemical or mechanical characteristics of the material.

Compothixo is a hand-held, battery-operated, vibration composite modeling instrument. When the device is turned on the unit begins to vibrate at 140 Hz. It functions in the same way as a hand-operated composite modeling instrument, and also has

interchangeable tips which are similar to the tips on manual composite modeling instruments. The main difference is the use of a battery-operated motor which activates vibrations in the tip, at frequencies which cannot be achieved by hand manipulation alone. Intermittent hand motion can achieve up to 4 Hz of vibration. Compothixo can also be hand operated when it is turned off. The rated voltage is 1.3V and rated current is 85 mA. Therefore, motor power consumption is 110 mW.

Compothixo is composed of the changeable tips, a chuck and the handle. The DC motor M is connected to the negative polarity of the battery housed in the handpiece, on the other side of the on/off switch. The latter connect the positive polarity of the battery to the motor depending on the status.

The handpiece is composed of an over molded elastomeric plastic, which encompasses the over molded plastic case.

Intended use of the Device

The Compothixo is a vibration instrument intended for composite modeling by dental professionals.

Technological Characteristics Compared to Predicate

The Compothixo is substantially equivalent to one legally marketed device in the United States. The Compothixo functions in a manner similar to and is intended for the same use as the Hu-Friedy Composite instrument manufactured Hu-Friedy.

Compothixo is similar to the Hu-Friedy Composite Instrument in that the shapes of the Compothixo tips used for the modeling of the composite are the same as used for the composite instrument. Both devices operate via movement of the tip across the surface of the newly placed composited material in the tooth. The frequency of the Compothixo instrument is about 140 Hz and the intermittent frequency of a hand operated composite instrument can reach up to 4 Hz. The Compothixo differs from the composite instrument in that the Compothixo is operated by an integrated vibration element powered by an AAAA alkaline battery in the handle which can be switched on or off according to the clinician's preference.

Non-Clinical Performance Data

Biocompatibility studies have been completed according to ISO 10993, which demonstrate that the material used to produce *Compothixo* is safe for its intended use. Additionally, *Compothixo* successfully passed electro-magnetic compliance (IEC 60601-1-2) testing at an independent testing laboratory.

This 510(k) submission also includes data from bench testing used to evaluate the performance characteristics of *Compothixo* to the predicate device, the Hu-Friedy Composite Instrument. The characteristics evaluated include Frequency of hand movement, Activation frequency, and Maximal radial amplitude of the modeling tip.

Clinical Testing

Clinical testing has not been conducted on this product.

Conclusion

Based upon the biocompatibility tests and bench testing, the clinical performance of *Compothixo* is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

KerrHawe SA
C/O Ms. Wendy Garman
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

JUL 25 2012

Re: K111465
Trade/Device Name: Compothixo
Regulation Number: 21 CFR 872.4565
Regulation Name: Dental Hand Instrument
Regulatory Class: I
Product Code: DZN
Dated: July 10, 2012
Received: July 11, 2012

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111465

Device Name: *Compothixo*

Indications for Use:
The Compothixo is a vibration instrument intended for composite modeling by dental professionals.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111465